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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,157	07/12/2002	Takashi Saito	NAII 118755	9352

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,157

Applicant(s)

SAITO, TAKASHI

Examiner

Richard Schnizer, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32,34,37-44,46,49-56,58,61-69,73,74,78,79,83-90 and 93-97 is/are pending in the application.
- 4a) Of the above claim(s) 84-90 and 93-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32,34,37-39,44,46,49-51,56,58,61-69,73,74,79 and 83 is/are rejected.
- 7) ☒ Claim(s) 40-43,52-55 and 78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/24/06 has been entered.

Claims 70, 75-77, 80, 91, and 92 were canceled as requested.

Claims 32, 34, 37-44, 46, 49-56, 58, 61-69, 73, 74, 78-80, 83-90, and 93-97 remain pending.

Claims 84-90 and 93-97 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/25/05.

Claims 32, 34, 37-44, 46, 49-56, 58, 61-69, 73, 74, 78, 79, and 83 are under consideration in this Office Action.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 9/09/1999 (11-255024). It is noted, however, that applicant

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has not filed a certified copy of the Japanese application as required by 35

U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56, 58, 61-69, 73, 79, and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 and dependent claims 58, 61-68, 79, and 83 are indefinite because claim 56 recites "said stimulus" without antecedent basis.

Claims 69 and 73 are indefinite because claim 69 does not provide proper antecedent basis for "said substance to be injected inside said membrane".

Substitution of "said desired substance" for "said substance to be injected inside said membrane" is suggested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 32, 34, 37-39, 44, 46, 49-51, 56, 58, 61-63, 66, 69, 74, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al (WO 96/07432), in view of Chen et al (US Patent 5,445,608).

Berg taught methods of delivering molecules to the cytosol of cells by delivering the molecule and a photosensitizer/photocatalyst to a cell, allowing cellular uptake of the molecule and photosensitizer in to the endosomal/lysosomal pathway, excitation of the photosensitizer with light of the appropriate wavelength, and release of the molecule from the endosome or lysosome, or other cellular compartment, without loss of cellular function. See paragraphs bridging pages 2-3 and 5-6. Contemplated photosensitizers included ALPcS_{2a}, which requires UV light for excitation. See e.g. page 10, lines 3-14. Although Berg did not explicitly teach recovery of perforated membranes, it would have been obvious to one of ordinary skill in the art at the time of the invention to adjust the concentration of photosensitizer, and/or the intensity or duration of light exposure, such that membrane damage was reversible in view of the stated objective of not losing cellular function.

Berg did not teach a membrane-destroying member, a supporting member that brings a photosensitizer and carries light from a light source, or a stimulus carrying member that locally introduces the light to a site in the membrane.

Chen taught methods of photodynamic therapy (PDT) by delivery of a photoreactive agent to a cell and illumination of the cell with stimulatory light. See abstract; column 1, lines 15-36; column 4, lines 3-16, column 5, lines 9-15 and column 7, lines 6-12. In particular, Chen taught that the method could be practiced with the

apparatus shown in Fig. 17 which allows one to deliver a photosensitizer through a catheter which also comprises an optical fiber. This arrangement allows precise illumination at the site of photosensitizer delivery. See column 23, line 42 to column 24, line 9; and column 24, lines 16-31. The catheter functions as the instantly recited capillary, and the optical fiber functions as the membrane destroying member, supporting member, and stimulus carrying member of the instant claims.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the apparatus of Chen in the method of Berg because the apparatus of Chen allows precise illumination at the site of photosensitizer delivery. See column 23, line 42 to column 24, line 9; and column 24, lines 16-31.

The photosensitizers of Berg and Chen are considered to be photocatalysts for the reasons of record at page 16 of the Action mailed 7/28/05, i.e. because they function by first being excited by light into an energized state, then transferring that energy to molecular oxygen to produce singlet oxygen, and to thereby return to the ground state and regenerate the photocatalyst.

Thus the invention as a whole was prima facie obvious.

Response to Arguments

Applicant's arguments filed 7/24/06 have been fully considered but they are not persuasive. Applicant argues at page 12 of the response that Berg does not disclose providing a stimulus so as to denature a selected site of a membrane. This is unpersuasive. Berg taught providing a photosensitizer to a cell, wherein the

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photosensitizer is taken up by the cell and subsequently associates with an intracellular membrane. Subsequent illumination of the photosensitizer results in excitation, generation of reactive oxygen species, and local damage to the membrane, i.e. damage to a selected area, that area that is inherently selected by proximity to the photosensitizer.

Applicant also argues that Chen does not teach denaturation of a selected site because Chen discloses perfusion of target cells with the photosensitizer. This is unpersuasive for the reasons set forth above. The photosensitizers are taken up by the cell, associate with sites in endosomes/lysosomes, and local damage to these sites occurs after photoexcitation. In this sense, the sites are “selected”.

This rejection could be overcome by amending the claims to make it clear that selection of a site in a membrane is an active method step. For example, the rejection of claim 32 could be overcome by insertion of “selecting a site on a membrane” immediately after “comprising”; substitution of “said” for “at least a”; and substituting “the” for “a” immediately before “selected site”.

Conclusion

No claim is allowed. Claims 40-43, 52-55, and 78 are objected to because they depend from a rejected claim(s), but would be allowable if rewritten in independent form comprising all of the limitations of the claim(s) from which they depend.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-

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272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Peter Paras, can be reached at (571) 272-4517. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

A handwritten signature in black ink, appearing to read 'Richard Schnizer', with a long horizontal line extending to the right.

Richard Schnizer, Ph.D.
Primary Examiner
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